

510(K) Summary

K080303

AUG - 6 2008

MEINNTech CO., LTD.
502, Pyeongchon IT B/D, 1113-1,
Daran-dong, dongan-gu,
Anyang-si, gyeonggi-do, Korea

Contact person: Contact : Ui-soo Kim, Overseas Sales Manager
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E-mail: peter@meinntech.com
Date Prepared: February 1, 2008

1. **Trade Name:** EZ Regular
Common Name: Intravascular administration set.
Classification Name: Intravascular administration set.
Product code FPA, Regulation: 880.5440
Class of device: Class II.
2. **The legally marketed device to which we are claiming equivalence [807.92(a)(3)] :**
Kipp Group Intravascular Administration Set (K991932)
3. **Description of device:** The EZ Regular consists of components commonly found on intravascular administration sets and extension sets.

EZ Regular set consists of various components such as:
 - air vented bag spike,
 - drip chamber with filter or without filter,
 - roller clamp, tubing,
 - flow controller,
 - Y-connector,
 - needle-less Y-connector,
 - luer lock end catheter,
 - manifold filter.
4. **Intended use:** The EZ Regular set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the patient's artery or vein. Prescription Use.
5. **Technological characteristics:** The EZ Regular Administration Sets and the predicate devices have identical technological characteristics and perform the same way as common intravascular administration sets. They are EO sterilized.
6. **Performance:** Bench tests were performed. Bench testing included biocompatibility, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2008

Meinntech Company, Limited
C/O Mr. Daniel Kamm
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K080303
Trade/Device Name: EZ Regular
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: July 29, 2008
Received: August 1, 2008

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

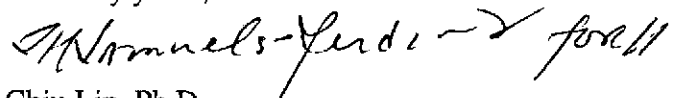
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", followed by a stylized flourish.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080303.

Device Name: EZ Regular

Indications For Use:

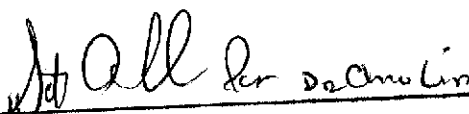
The EZ Regular set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into the patient's artery or vein.

Prescription Use X AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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